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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,807	01/17/2001	Maria Palasis	12013/58101	4398
26646	7590	06/15/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 06/15/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/760,807	<b>Applicant(s)</b> PALASIS, MARIA	
	<b>Examiner</b> LoAn H. Thanh	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6-15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,7,11,13,15,17-19,22 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8-10,12,14,20-21,23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Claims 4, 6-7, 11, 13, 15, 17-18, 19, 22, 25-27 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/24/04.

This application contains claims 7 and 17 drawn to an invention nonelected with traverse in the reply filed on 03/24/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's election with traverse of species of figs. 6-7 and subspecies i (exterior surface covered with therapeutic) in the reply filed on 03/24/04 is acknowledged. The traversal is on the ground(s) that the claims were previously presented and the office action lacks the required explanation. This is not found persuasive because applicant is now amending the claims and narrowing the scope of the claims which are directed to one of the a plurality of embodiments which are disclosed in the specification. A Applicant's proper response to restriction should be directed to the species being not patentably distinct. See page 3 of the last office action. The explanation of the restriction is clear. There is a plurality of species disclosed and applicant is required to make an election. Upon allowance of a generic claim applicant is entitled to consideration of the claims as outlined on page of the last office action. Further, the

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search is a burden since the search is no longer being updated but re-searched in view of the amended claims.

The requirement is still deemed proper and is therefore made FINAL.

### ***Response to amendments***

The specification objection has been withdrawn in view of applicant's arguments filed 12/02/03.

The amended drawing of fig. 5 is not clearly disclosed in the specification. For the figure to be introduced at this time would be to introduce new matter. The drawing could have been introduced in many different matters. The drawing is not an issue at this time since the claims have been withdrawn in view of the elected embodiment.

With respect to the IDS, filed 04/04/03, the U.S. references were cited on the PTO -892 as a courtesy which means it has been cited and considered. For those references which has not been cited, they have not been considered. Further, with respect to the new IDS submitted 12/03/04, applicant is requested to supply the PTO-1449 form since there is no record of the listing. However there is a cover letter and a receipt of the papers. The IDS will be considered when resubmitted.

### ***Information Disclosure Statement***

The information disclosure statement filed 04/04/03 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office.

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There is a letter and postcard receipt of an IDS submitted. However there is no PTO-1449 listing of references. Applicant is requested to submit another copy of the filed PTO-1449 to be considered.

### ***Drawings***

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 11/25/02 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(f) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of grooves as characterized in the amended figure 5.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second balloon positioned between the dilation bladder and the first balloon and the grooves in the first balloon must be shown or the feature(s) canceled from the claim(s). **No new matter should be entered.**

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claims 2-3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

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Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claim 1 has been amended to include an exterior surface partially covered with a therapeutic. It is unclear what applicant is intending to further limit since claims 2-3 only recites the exterior surface having a therapeutic a in contact with the balloon or that the source of the therapeutic is with the exterior of the balloon.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2-3,8-10, 20-21,23, are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al. ( U.S. Patent No. 5,295,962).

Crocker et al. teach a system comprising a catheter, a source of fluid, a first inflatable balloon (32) having a measurable elasticity, and a dilatation bladder (30) having a measurable elasticity wherein the elasticity of the first balloon is greater than the dilatation bladder. Crocker et al. disclose the first balloon to be made of an elastic material such as latex located within the first balloon ( 32). See col. 7, lines 16-18. Further, Crocker et al. teach the dilatation bladder to be of a relatively non-elastic material. ( see col. 6, lines 48-53.) and that the application of the device is to dilate a stenotic region of a body lumen as desired. ( col. 6, lines 67-col. 7, line 2. ) See col. 4, lines 25-29 .

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,7-10, 12,14,20-21,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,471,672) or Abele et al. ( US Patent No. 5,704,913) in view of Sahatjian (US Patent No. 5,304,121).

Brown et al./ Abele et al. disclose a balloon catheter having dilation balloon with an inflation lumen and an outer balloon with a second inflation lumen for use in the blood vessel for angioplasty. See col. 5 and figures 1-3, and 7 of Brown et al. ( See figures of Abele et al. ). However, Brown et al./Abele et al. does not disclose a coated outer balloon. Sahatjian discloses a balloon catheter having a therapeutic material on the exterior surface of the balloon in the analogous art of angioplasty and balloon catheters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Brown et al./Abele et al. with a coating as taught by Sahatjian in order to provide direct treatment of therapeutic material onto the target tissue of the blood vessel.

With respect to claim 9, they do not disclose silicone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the materials of the balloon with silicone as a well known material used in balloon catheters, since it has been held to be within the general skill of a worker in the art to

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select a known material on the basis of its suitability for the intended uses as a matter of obvious engineering choice lacking any criticality. In re Leshin , 125 USPQ 416.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-4,6,8-12,14-15,19,20-23,25 have been considered but are not persuasive.

With respect to applicant/s arguments on page 14 of the arguments filed 12/02/03, Applicant has only broadly claimed that “the exterior surface is at least partially covered with a therapeutic when the first balloon is in an initial unexpanded state” . Crocker ‘s device is capable releasing the drug through the pores in an unexpanded state. When this occurs the drug will be “partially cover the balloon”.

Crocker et al. teaches in column 4, lines 25-29, that the inflation can be selectively introduced with respect to applicant’s amended limitation of inflating the first balloon without inflating the dilation bladder.

The Crocker et al. reference has been withdrawn from claim 12 (and it's dependent claims) and claim 21 since it requires the surface to be impervious.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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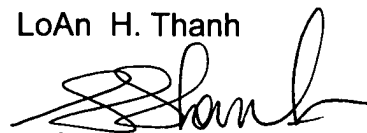
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LoAn H. Thanh

  
**LOAN H. THANH**  
**PRIMARY EXAMINER**